PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



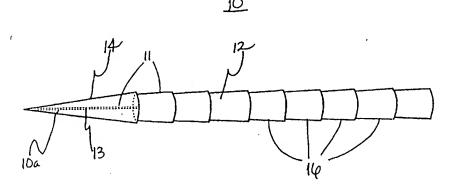
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT) (51) International Patent Classification 7: (11) International Publication Number: WO 00/67659 A1 A61C 5/04, 13/30 (43) International Publication Date: 16 November 2000 (16.11.00) (81) Designated States: AU, BR, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, PCT/US00/13021 (21) International Application Number: (22) International Filing Date: 12 May 2000 (12.05.00) MC, NL, PT, SE). (30) Priority Data: Published 12 May 1999 (12.05.99) US With international search report. 60/133,773

(71) Applicant: JENERIC/PENTRON INCORPORATED [US/US]; 53 North Plains Industrial Road, Wallingford, CT 06492-0724 (US).

(72) Inventors: LOPEZ, Larry, A.; 522 Pleasant Valley Drive North, Boerne, TX 78006 (US). FINNIGAN, Bruce, A.; 177 Washington Street, Wallingford, CT 06492 (US). KARMAKER, Ajit; 321 South Elm Street, Wallingford, CT 06492 (US).

(74) Agent: REIMER, Leah, M.; Cantor Colburn LLP, 55 Griffin Road South, Bloomfield, CT 06002 (US).

(54) Title: ENDODONTIC POST SYSTEM



(57) Abstract

An endodontic post comprising a combined endodontic post and filling material tip in a single unit. To use the post unit, the device is placed in an oven or heater to heat and soften the thermoplastic material. The device will then be placed in a root canal that has been opened to a predetermined dimension by use of endodontic files, to seal the apical end. If necessary, the gutta percha can be compacted toward the apex, while it is still in the softened state, to ensure the apex is adequately sealed. The post is then cemented into place by lining the canal walls with a bonding agent and filling the interface between the post and the walls of the canal with a dual cure resin cement. This will result in a coronal seal of the canal via resin restorative material and an apical seal of the canal by means of gutta percha and sealant.

INSDOCID: <WO_____0067659A1_I_>

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

Albania	ES	Spain	เร	Lesotho	SI	Slovenia
Armenia	Fl	Finland	LT	Lithuania	SK	Slovakia
Austria	FR	France	LU	Luxembourg	SN ·	Senegal
Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
Belgium	GN	Guinca	MK	The former Yugoslav	TM	Turkmenistan
Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
Brazil	IL	Israel	MR	Mauritania	UG	Uganda
Belarus	IS	Iceland	MW	Malawi	US	United States of America
Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
Switzerland	KG	Kyrgyzstan	NO	Norway	zw	Zimbabwe
Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
Cameroon		Republic of Korea	PL	Poland		
China	KR	Republic of Korea	PT	Portugal		
Cuba	KZ	Kazakstan	RO	Romania		
Czech Republic	LC	Saint Lucia	RU	Russian Federation		
Germany	U	Liechtenstein	SD	Sudan		
Denmark	LK	Sri Lanka	SE	Sweden		
Estonia	LR	Liberia	SG	Singapore		
	Armenia Austria Austria Azerbaijan Bosnia and Herzegovina Barbados Belgium Burkina Faso Bulgaria Benin Brazil Belarus Canada Central African Republic Congo Switzerland Côte d'Ivoire Cameroon China Cuba Czech Republic Germany Denmark	Armenia FI Austria FR Austria GA Azerbaijan GB Bosnia and Herzegovina GE Barbados GH Belgium GN Burkina Faso GR Bulgaria HU Benin IE Brazil IL Belarus IS Canada IT Central African Republic JP Congo KE Switzerland KG Côte d'Ivoire KP Cameroon China KR Cuba KZ Czech Republic LC Germany LI Denmark LK	Armenia FI Finland Austria FR France Australia GA Gabon Azerbaijan GB United Kingdom Bosnia and Herzegovina GE Georgia Barbados GH Ghana Belgium GN Guinea Burkina Faso GR Greece Bulgaria HU Hungary Benin IE Ireland Brazil IL Israel Belarus IS Lecland Canada IT Italy Central African Republic JP Japan Congo KE Kenya Switzerland KG Kyrgyzstan Côte d'Ivoire KP Democratic People's Rameroon Cameroon RR Republic of Korea Cuba KZ Kazakstan Czech Republic LC Saint Lucia Cermany LI Liechtenstein Denmark LK Sri Lanka	Armenia FI Finland LT Austraia FR France LU Austraiia GA Gabon LV Azerbaijan GB United Kingdom MC Bosnia and Herzegovina GE Georgia MD Barbados GH Ghana MG Belgium GN Guinca MK Bulgaria HU Hungary ML Benin IE Ireland MN Brazil IL Israel MR Canada IT Italy MW Canada IT Italy MX Central African Republic JP Japan NE Congo KE Kenya NL Switzerland KG Kyrgyzstan NO Côte d'Ivoire KP Democratic People's NZ Republic of Korea PL Cuba KR Republic of Korea PT Cuba KZ Kazakstan	Armenia FI Finland LT Lithuania Austria FR France LU Luxembourg Australia GA Gabon LV Larvia Azerbaijan GB United Kingdom MC Monaco Bosnia and Herzegovina GE Georgia MD Republic of Moldova Barbados GH Ghana MG Madagascar Belgium GN Guinea MK The former Yugostav Burkina Faso GR Greece Republic of Macedonia Bulgaria HU Hungary ML Mali Benin IE Ireland MN Mongolia Brazil IL Israel MR Mauritania Belarus IS Iceland MW Malawi Canada IT Italy MX Mexico Central African Republic JP Japan NE Niger Congo KE Kenya NL Netherlands Switzerland KG Kyrgyzstan NO Norway Côte d'Ivoire KP Democratic People's NZ New Zealand Cameroon Republic of Korea PL Poland China KR Republic of Korea PL Poland Czech Republic LC Saint Lucia RU Russian Federation Czech Republic LC Saint Lucia RU Russian Federation Demmark LK Sri Lanka SE Sweden	Armenia FI Finland LT Lithuania SK Australa FR France LU Luxembourg SN Australia GA Gabon LV Latvia SZ Azerbaijan GB United Kingdom MC Monaco TD Bosnia and Herzegovina GE Georgia MD Republic of Moldova TG Barbados GH Ghana MG Madagascar TJ Belgium GN Guinca MK The former Yugoslav TM Bulgaria HU Hungary ML Mali TT Benin IE Ireland MN Mongolia UA Brazil IL Israel MR Mamiritania UG Belarus IS Iccland MW Malwi US Canada IT Italy MX Mexico UZ Central African Republic JP Japan NE Niger V

BNSDOCID: <WO_____0067659A1_I_>

1

ENDODONTIC POST SYSTEM

Field of the Invention

This invention relates to both the obturation of a root canal having undergone endodontic treatment and the simultaneous placement of an endodontic post system.

Background of the Invention

Endodontics or root canal therapy is that branch of dentistry dealing with the diseases of the dental pulp and associated tissues. One aspect of endodontics comprises the treatment of infected root canals, the removal of diseased pulp tissues, followed by the biomechanical modification and the subsequent filling of the pulp canal (root canal). Root canal therapy is generally indicated for teeth having sound external structures but having diseased, dead or dying pulp tissues. Such teeth may or may not generally possess intact enamel and dentin and be satisfactorily engaged with bony tissue. In such teeth, the pulp tissue and excised portions of the root should be replaced by a biocompatible substitute.

One technique for the preparation of a root canal involves creating a coronal access opening with a conventional dental drill. A tool is used for gross removal of pulp material from the root canal through the coronal access opening. The void formed is enlarged with reamers and/or files to result in a fully excavated cavity. Debris is removed from this cavity by flushing and the cavity is cleansed to remove

INSDOCID: <WO_____0067659A1_1>

5

10

WO 00/67659

5

10

15

20

25

30

all diseased tissue. Following chemical antisepsis, the excavated canal is ready for filling.

A basic method involves inserting a filling cone into a root canal and cementing therein to obturate the canal. Lateral condensation is a method in which several filling cones, a primary cone and auxiliary cones, are inserted into a root canal. The primary cone is inserted and cemented to the seat of the root canal. Using a tapered spreader, the primary cone is then squeezed against the side of the root canal and a second cone is inserted and cemented into place. This process is continued until the root canal is completely obturated, which can require up to 10 to 15 filling cones.

Vertical condensation of warm or hot gutta percha is yet another method of sealing root canals. After cementing a primary cone short of the apex of the root canal, heat application is alternated with a series of smaller and smaller pluggers until the gutta percha is moved to the apex. This is often possible when the smallest plugger approaches the apex of the tooth within 3 to 5 millimeters. The space is then backfilled. Lateral canals are packed and sealed as a consequence of lateral expansion of a wave of heated gutta percha. Alternatively, small segments of gutta percha can be used in this method that are inserted into the root canal, heated in order they can adhere to one another and each backfilled one at a time until the root canal is filled. All three of these methods, the single filling cone, lateral condensation and vertical condensation apply root canal cement or sealer around the individual cones or in between segments as a binding agent. Another method employs an injection gun that injects warm or hot gutta percha filling material into a root canal. The injector initially places heated gutta percha at the seat of the root canal which is then condensed with a plugger into the root tip. The injector then backfills the root canal by injecting additional gutta percha into the root canal until it is obturated. A similar method involves heating gutta percha on a flexible metal carrier used to insert the gutta percha into the root canal. The carrier may be a solid rod, or a hollow rod, situated in the center of a master cone. The rod is connected to a handle which may be removed by slipping it out of the hollow rod, or cutting it off if it is a solid rod.

NSDOCID: <WO_____0067659A1_1_>

While these systems provide for convenient and quick obturation of the canal, they pose a removal problem for the dentist who has to place a post.

Of all the methods used for obturating a canal, there is no device currently available that will allow a doctor to simultaneously obturate a root canal and place an endodontic post. Currently, an endodontist will perform the root canal procedure and the obturation during one patient visit. After the canal is obturated and temporarily sealed, the patient is frequently treated by a second dentist who will place the post. To do so, the gutta percha must be removed from the canal until only a portion (about 5 mm) from the apex remains to act as an apical seal. The rods inside the current systems make gutta percha removal much more difficult since the coronal portion of the gutta percha rod has to be removed to allow for the placement of the endodontic post. One way to overcome this problem has been to notch the obturating rod with a bur. Then, when the obturator is placed in the canal it is twisted, snapping off the apical portion. The longer coronal portion is removed. It is then re-introduced into the canal and the gutta percha is stripped off by means of pulling the rod through an endodontic stop. Since the endodontic stop is extremely narrow, the gutta percha is pulled from the rod as it is withdrawn and the gutta percha remains in the canal. It is subsequently condensed. As a result of this technique, the restoring dentist does not have to extract the rod and only has to remove the gutta percha to make room for the post. Some gutta percha may remain on the walls of the canal jeopardizing the bond strength of the post the radicular dentin. Reinfection of the treated tooth can be a problem because the endodontist performing the root canal procedure will seal the coronal opening with a temporary stopping agent which can leak oral fluids carrying bacterial into the canal opening.

It is desirable to reduce the steps and time involved in performing obturation and placement of a post in a root canal. It would be beneficial to limit the obturation and post placement to a single visit to the dentist or prosthodontist. It is advantageous to reduce and/or eliminate the leakage problems associated with poor sealing at the coronal end of the canal.

Summary of the Invention

BNSDOCID: <WO____0067659A1_I_>

5

10

15

20

25

10

15

20

25

4

These and other objects and advantages are accomplished by the endodontic post of the present invention comprising a combined endodontic post and tip of filling material such as thermoplastic material in a single unit. To use the post unit, the tip of the device is softened by placing in an oven or heater to heat and soften the filling material or chemically treating to soften the material. The device is be placed in a root canal that has been opened to a predetermined dimension by use of endodontic files, to seal the apical end. If necessary, the gutta percha can be compacted toward the apex, while it is still in the softened state, to ensure the apex is adequately sealed. The post may then be cemented into place by lining the canal walls with a bonding agent and filling the interface between the post and the walls of the canal with a resin cement such as a dual cure cement, a light cure cement or a self cure cement such as Lute-It® dual cure luting cement or Cement-It® Universal cement, both available from Jeneric/Pentron Inc., in Wallingford, CT. This will result in a coronal seal of the canal via resin restorative material and an apical seal of the canal by means of gutta percha and sealant. The remaining portion of the post, extending supra-gingivally, will be used to build a core around it. Any excess will be cut off. One length of the device will be longer to accommodate the longer roots in anterior teeth. Another length will be shorter to accommodate smaller roots in the molar region. Various diameters may also be provided to accommodate the different sizes of root canals. The bonded flexible post may strengthen the tooth to prevent subsequent root fractures.

Brief Description of the Drawings

Features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

Figure 1 is an elevational view of a post in accordance with the invention;

Figure 2 is an elevational view of a post with an alternate carrier in accordance with the invention;

Figure 3 is a sectional view of a tooth showing a post of the invention placed

ISDOCID: <WO_____0067659A1_I_>

PCT/US00/13021

5

in the root canal; and

WO 00/67659

5

10

15

20

25

30

Figure 4 is an elevational view of an alternate embodiment of a post in accordance with the invention.

Description of the Invention

As will be appreciated, the present invention provides a combination endodontic post and filler cone in a single unit. Reference is made to Figures 1 and 2 which show a post unit 10 comprising a post section 11 and a cone or tip section 14. Tip section 14 comprises a flexible rod or cone of biocompatible material for filling the apex of the canal. The filling material is typically a thermoplastic, chemo-plastic, or similar resinous material, such as gutta percha and is attached to post section 11 at the apical end 10a. Other examples of thermoplastic materials include but are not limited to thermoplastic methacrylate materials, polyurethanes, polypropylene and polyethylene.

The filling material may include additives typical in the dental field such as plasticizing, cariostatic, antibacterial, or other anti-inflammatory, biologically active or therapeutic materials.

Post section 11 comprises a main body or endodontic portion 12 and a carrier or apical portion 13 which is located at the apical end 10a of post unit 10. Main body 12 may be a solid rod of circular or other suitable cross-section comprising a substantially smooth surface or may comprise a plurality of frustoconical sections 16 arranged coaxially along the longitudinal axis of main body 12. Preferably, main body 12 has consistent width along the longitudinal axis thereof whereas frustoconical sections 16 each have the same tapered width and same length. It is possible to vary the width and/or length of main body 12 and/or vary the tapered width and/or length of frustoconical sections 16 along the longitudinal axis of main body 12. Main body 12 may include a larger head of any shape with or without a retentive design to provide support for a core thereon at the supracoronal end 12h as will be discussed hereinafter.

Carrier 13 is preferably an extension of main body 12 of post section 11 and is of very fine diameter to accommodate tip section 14 of thermoplastic material of post

BNSDOCID: ∠WO 0067659A1 (>

6

unit 10. In one method of manufacture which will be discussed hereinafter, post section 11 is manufactured from a rod of material that is cut or machined at the apical end 10a to result in carrier 13 having a very small width or diameter in comparison to main body 12. Carrier 13 is of small diameter to allow enough area to form tip section 14 thereon, and also of enough strength and integrity to accommodate the filling material such as thermoplastic material. As stated above, carrier 13 is preferably an extension of main body 12 and is shown having constant diameter along the length thereof, but may be of any shape or size sufficient to hold tip section 14 thereon. Figure 2 shows an alternative carrier 13 of tapered width.

Post section 11 may be fabricated of any material to provide a flexible apical portion and a more rigid endodontic and/or coronal or supracoronal portion, such as metal, plastic, ceramic, polymeric, composite, or other material suitable for placement in the mouth. Composite materials include but are not limited to filler reinforced composite materials and fiber reinforced composite materials comprising the reinforcing component in a polymeric matrix material such as those composite materials listed in U.S. Patent Nos. 4,717,341 and 4,894,012 to Goldberg et al., U.S. Patent No. 6,039,569 to Prasad et al., U.S. Patent No. 6,030,220 to Karmaker et al, U.S. Patent No. 5,564,929 to Alpert, and U.S. Patent No. 5,919,044 to Sicurelli, Jr. et al., all of which are hereby incorporated by reference. The fiber reinforced composite material may comprise fibers in the form of long, unidirectional, continuous filaments which are preferably at least partially aligned and oriented along the longitudinal dimension of the component with alignment normal or perpendicular to that dimension also possible. The fibers may be of uniform or random length, unidirectional or multidirectional, or randomly dispersed, and may be as short as about 3 to about 4 millimeters (mm) or shorter. The fibers may also be in the form of fabric as set forth in copending Serial No. 09/280,760 filed March 29, 1999 and may include any of the attributes of the post described therein, the contents all of which are hereby incorporated by reference. Due to the improved structural integrity, the amount of fibers in the structural component preferably equals at least about 20% by weight (wt %) and preferably about 20 wt % to about 70 wt %. Possible reinforcing fibers, which are preferably used in accordance with U.S. Pat. Nos. 4,717,341 and

BNSDOCID: <WO_____0067659A1_l_>

5

10

15

20

25

7

4,894,012 to Goldberg et al. (which are herein incorporated by reference), include glass, ceramic, metal, carbon, graphite, polymeric such as cellulose, polyamide, aramid, polyester, polyaramid, acrylic, vinyl and modacrylic, polyolefin, polytetrafluorethylene, mixtures thereof, as well as other fibers known in the art. One preferred version of the device is comprised of unidirectional microfilamentous glass fibers bundled in a resin matrix.

In order to enhance the bond between the fibers and polymeric matrix, thereby enhancing the reinforcing effect, the fibers may be silanized or otherwise treated such as by grafting functional monomers to obtain proper coupling between the fibers and the resin matrix. Silanization renders the fibers hydrophobic, reducing the water sorption and improving the hydrolytic stability of the composite material, renders the fibers organophilic, improving wetting and mixing, and bonds the fibers to the polymeric matrix. Typical silane is A-174 (p-methacrylate propyl tri-methoxy silane), produced by OSI Specialties, New York The polymeric matrix is selected from those known in the art of dental materials, including, but not limited to, polyamides, polyester, polyolefins, polyimides, polyarylates, polyurethanes, vinyl esters or epoxy-based materials, styrenes, styrene acrylonitriles, ABS polymers, polysulfones, polyacetals, polycarbonates, polyphenylene sulfides, polyarylsulfides, acrylonitrile-butadiene-styrene copolymers, polyurethane dimethacrylates (hereinafter abbreviated to PUDMA), and the like. Preferred polymeric matrix materials include those based on acrylic and methacrylic monomers, for example those disclosed in U.S. Patent Nos. 3,066,112, 3,179,623, and 3,194,784 to Bowen; U.S. Pat. Nos. 3,751,399 and 3,926,906 to Lee et al.; and commonly assigned U.S. Pat. Nos. 5,276,068 to Waknine (which are herein incorporated by reference). An especially preferred methacrylate monomer is the condensation product of bisphenol A and glycidyl methacrylate, 2,2'-bis [4-(3-methacryloxy-2-hydroxy propoxy)-phenyl]propane (hereinafter abbreviated "BIS-GMA").

The polymer matrix, which typically includes polymerization initiators, polymerization accelerators, ultra-violet light absorbers, anti-oxidants, fluorescent whitening agents, free radical initiators, and/or other additives well known in the art, may be visible light curable, self-curing, dual curing, or vacuum, heat, or pressure

NSDOCID: <WO_____0067659A1_I_>

5

15

20

25

8

curable compositions, as well as any combination thereof. Heat and pressure or vacuum curable compositions include a heat cure initiator such as benzoyl peroxide, 1,1'-azobis(cyclohexanecarbo-nitrile) or other free radical initiators. The preferred polymeric matrix is a light and heat curable matrix, wherein light effects partial cure of the polymer matrix, while final curing is by heat under controlled atmosphere.

Fillers may be present in addition to or instead of fibers in an amount up to about 80 wt %, and preferably about 70 wt%. If fibers are present, the amount of filler is present in an amount of up to about 30 wt % of one or more fillers known in the art and used in dental restorative materials. Suitable fillers include those capable of being covalently bonded to the polymeric matrix itself or to a coupling agent that is covalently bonded to both. Fillers include silica, silicate glass, quartz, barium silicate, strontium silicate, barium borosilicate, strontium borosilicate, borosilicate, lithium silicate, amorphous silica, ammoniated or deammoniated calcium phosphate and alumina, zirconia, tin oxide, and titania, among other conventional fillers such as those disclosed in commonly assigned U.S. Pat. Nos. 4,544,359 and 4,547,531 to Waknine (which are incorporated herein by reference), while possible coupling agents include silanes, zirconates, and titanates. If the post is manufactured from a composite material, it is preferably in completely cured or hardened state.

Examples of metals useful as post section 11 include but are not limited to metals or alloys of Pd, Pt, Rh, Ir, Au, Ag, Ti, Co, Mo and alloys thereof such as AgPd, AuPtPd, TiAlFe, TiAlV,CoCrMo, stainless steel and brass. Ceramic materials useful in the fabrication of post section 11 include but are not limited to alumina, zirconia, mullite, spinel, porcelain, titania, lithium disilicate, leucite, amorphous glass, lithium phosphate, and combinations thereof, or any high strength ceramic material which can withstand the stresses created in the mouth.

In accordance with one method of manufacture herein, post section 11 (which includes main body 12 and carrier 13) is manufactured in any known method in the art and depending upon the material used for the manufacture of post section 11. Such methods include but are not limited to matched die processes, autoclave molding, resin injection molding (RIM), sheet, dough and bulk molding, press molding, injection molding, reaction injection molding, resin transfer molding

3NSDOCID: <WO_____0067659A1_I_>

5

10

15

20

25

10

15

20

25

30

(RTM), compression molding, open molding, hand rolling, dipping and rolling, pressing, extrusion, pultrusion and filament winding. As discussed above, post section 11 is formed into a rod-shaped unit or main body 12 having a very fine or thin apical end or carrier 13. The final shape of post section 11 may be formed simultaneously during the manufacturing process thereof. Alternatively, a rod shaped material may be manufactured and thereafter shaped by grinding, cutting, milling or the like into the desired shape and size. As shown in Figures 1 and 2, post section 11 is a rod-shaped component having a main body 12 comprising slightly tapered stepped sections 16, all of the same dimensions and whereby one end of post section 11 comprises a very narrow section, 13, which acts as the carrier for the filling material. As with sections 16, carrier 13 may be formed during the actual manufacture of main body 12 or thereafter by grinding, cutting or similar means. Although main body 12 includes sections 16 to aid in the retention of the post in the canal, main body 12 may be of any surface (e.g., smooth, partly smooth and partly frustoconical,) and shape suitable for placement in the canal such as in the case of smaller diameter posts whereby the ledges may be eliminated so as to maintain the structural integrity and strength of the post. Carrier 13 preferably comprises a smooth surface, although it is in no way limited to such and may be of any surface suitable for application of filling material thereon. The post may be provided in an opaque tooth color or it may be colored similar to a tooth's pulp for enhanced esthetics. The post may include an appropriate amount of raadiopaque material such as titanium oxide, barium sulfate, and similar materials known in the dental industry to insure xray documentation which may be added to the post material during manufacture thereof.

After post section 11 has been manufactured, carrier 13 of post section 11 is then coated with a filling material such as gutta percha to obtain cone section 14 thereon. The filling material may be applied by any known means such as dipping, injection molding, hand rolling, and the like.

The length of post unit 10 may vary depending upon the length of the root into which it will be inserted. It is preferable that post 10 be manufactured in a variety of lengths and widths to fit the many different root canals of dental patients and the

BNSDOCID: <WO 0067659A1 1 >

10

differing lengths of the anterior (central and lateral incisors, bicuspids and premolars) and molar teeth. Preferably, post unit 10 is about 14 to about 31 mm in length and more preferably about 16 to about 25 mm in length. For the length parameter, post section 11 may be divided into three sections. Section 13 is the apical section and is about 3 to about 12 mm in length and preferably about 5 to about 8 mm in length. If section 13 is tapered as in Figure 2, the taper may be continuous at about 0.02 mm/per mm or less from the apical tip 13t to the end 13e of carrier 13, or preferably 0.04mm/per mm from the apical tip 13t to the end 13e of carrier 13. As stated above, carrier 13 is covered with a filling material such as a thermoplastic material which does not extend more than a few mm in length past the tip of 13 (13t). Main body 12 comprises a main section from point 13e to point 12m which is about 5 to about 13 mm in length and preferably about 7 to about 11 mm in length, and a supracoronal portion or "head" of post section 11 from point 12m to point 12h which about 2 to about 8 mm and more preferably about 4 to about 6 mm in length. The supracoronal portion of post unit 11 will be used to build a core upon which a crown will be placed. The main section (from 13e to 12m) of main body 12 of post section 11 may be slightly flexible to negotiate curved canals.

The diameter of post section 11 will also vary and range from about 0.02 to about 0.15 at the apical end (13t - 13e) and preferably from about 0.02 to about 0.09 at the apical end (13t - 13e). If carrier 13 is tapered, the diameter at 13t is in the range of about 0.02 to about 0.15 and preferably about 0.05 to about 0.16 mm and the diameter at 13e is in the range of about 0.26 to about 0.26 and preferably about 0.26 to about 0.26 to about 0.26 to about 0.26 to about 0.26 and preferably about 0.26 to about 0.26 to

Tip section 14 comprising the filling material is about 0.5 to 1 mm longer than carrier 13, but the diameter of tip section 14 is tapered from point 13e to point 13t in accordance with ISO standards to correspond to current obturating techniques utilizing master cones of thermoplastic material. Accordingly, tip section 14 can be tapered at least 0.02 mm/per mm in accordance with ISO standards, and preferably 0.04 or 0.06 mm/per mm, or greater, measuring from tip 14t to 14e, for insertion into canals created with 0.02, 0.04,0.06, or greater, tapered files. The diameter of tip 14

BNSDOCID: <WO_____0067659A1_I_>

5

10

15

20

25

5

10

15

20

25

30

at point 14e is in the range of about 0.30 to about 2.0 mm and preferably 0.40 to about 1.5 mm. The diameter of tip 14 at point 14 t is in the range of about 0.20 to about 1.0 mm and preferably about 0.25 to about 0.80 mm. When using the post unit in canals of 0.02 taper, the filling material such as thermoplastic material will be compressed by the canal and forced toward the coronal end of the canal. This will result in an apical seal in excess of 8 mm. The excess thermoplastic material can be removed with a heated instrument after it has hardened. When using the post unit in 0.06 tapered canals, the filling material can be condensed down toward the apex to fill the void created by the greater taper. This will result in an apical seal less than 8 mm, but in excess of 4 mm which is sufficient to maintain the apical seal.

To use the post unit, the device is placed in or near an oven or heater to heat and soften the filling material or dipped in a chemical solution such as chloroform to soften the filling material. The device will then be placed in a root canal that has been opened to a predetermined dimension by use of endodontic files, to seal the apical end. If necessary, the gutta percha can be compacted toward the apex, while it is still in the softened state, to ensure the apex is adequately sealed. The post is then cemented into place by lining the canal walls with a bonding agent and filling the interface between the post and the walls of the canal with a resin cement, such as a dual cure cement. This will result in a coronal seal of the canal via resin restorative material and an apical seal of the canal by means of gutta percha and sealant. The remaining portion of the post, extending supra-gingivally, will be used to build a core around it, and if necessary, for placement of a crown thereon. Any excess of the post will be cut off. One length of the device will be longer to accommodate the longer roots in anterior teeth. Another length will be shorter to accommodate smaller roots in the molar region.

Figure 3 shows a root canal 30 with post unit 32 therein. Post unit 32 comprises a post section 33 having a main body 34 and a carrier 36 that carries the filling material 38. As shown in Figure 3, the thermoplastic material 38 was softened prior to insertion and fills the apex of the canal.

In an alternate embodiment herein, reference is made to Figure 4 wherein a post unit 40 comprises a post section 42 fabricated of fiber reinforced composite

ISDOCID: <WO_____0067659A1_i_>

12

material wherein the fibers comprise optical fibers 44 such as glass fibers or a central core of a material such as metal which is able to transmit heat energy to the filling material. Glass fibers 44 extend out through post section 42 into carrier 46 and tip section 48. To use the post unit 40, the filling material 48 does not have to be softened or heated prior to insertion into the canal. Post unit 40 is inserted into the canal with tip 48 in its hardened state. A curing light or other heat source is applied to the coronal portion of the post, transmitting light or heat down toward the apex. Fibers 44 convert the light into heat or, alternatively, the core section transmits heat to the filling material. The heat then plasticizes the filling material such as gutta percha at the apex. The post is then pushed toward the apex using gentle finger pressure. This last step insures that the plasticized gutta percha is compressed apically and laterally, sealing the tooth and any lateral canals.

One of the benefits of this alternative embodiment is that it insures plasticized gutta percha is only introduced to the apical portion of the root and that the coronal portion of the root is free of gutta percha which could negatively affect the retentive strength of the post/core.

While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein. Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.

ISDOCID: <WO_____0067659A1_I_>

5

10

15

20

What is claimed is:

- 1. An endodontic post comprising:
- a post section; and
- a tip section, wherein the tip section comprises a filling material.
- 2.. The endodontic post of claim 1 wherein the tip section is integral to the post section.
- The endodontic post of claim 1 wherein the post section comprises an apical portion and an endodontic portion and wherein the apical portion comprises a carrier.
- 4. The endodontic post of claim 3 wherein the carrier extends into the tip section.
 - 5. The endodontic post of claim 3 wherein the carrier is flexible.
- 6. The endodontic post of claim 3 wherein the apical portion of the post is narrower in diameter than the diameter of the endodontic portion.
- 7. The endodontic post of claim 3 wherein the post further comprises a supracoronal portion.
- 8. The endodontic post of claim 1 wherein the post section is fabricated of metal, plastic, composite, ceramic, glass or polymeric material.
- 9. The endodontic post of claim 1 wherein the filling material comprises a thermoplastic or chemoplastic material.
- 10. The endodontic post of claim 1 wherein the filling material comprises a polymeric material.

11. The endodontic post of claim 1 wherein the filling material comprises gutta percha.

12. A method for restoring the root canal of a tooth comprising: preparing the root canal;

providing a post for insertion into the canal, whereby the post comprises a post section, and a tip section, wherein the tip section comprises a filling material;

softening the tip section of the post;

inserting the post into the canal, whereby the root canal is sealed by the filling material.

- 13. The method of claim 12 further comprising inserting a sealing material into the canal to bond the post to the canal.
- 14. The method of claim 12 further building a core on an end of the post that extends from the canal.
 - 15. The method of claim 14 further comprising placing a crown on the core.
 - 16. A method for restoring the root canal of a tooth comprising: preparing the root canal;

providing a post for insertion into the canal, whereby the post comprises a post section, and a tip section, wherein the tip section comprises a filling material, and wherein the post section comprises optical fibers, whereby the optical fibers extend into the tip section and wherein the upper end of the post section is the coronal end and the bottom of the tip section of the post is the apical end;

inserting the post into the canal;

applying a heat source to the coronal end of the post, whereby the heat source heats the fibers, and whereby the heated fibers soften the filling material located on the tip section, whereby the softened filling material seals the root canal.

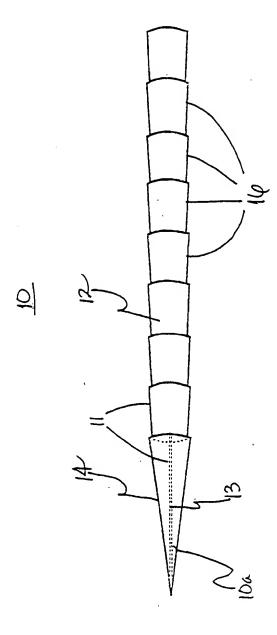
BNSDOCID: <WO_____0067659A1_l_>

5

10

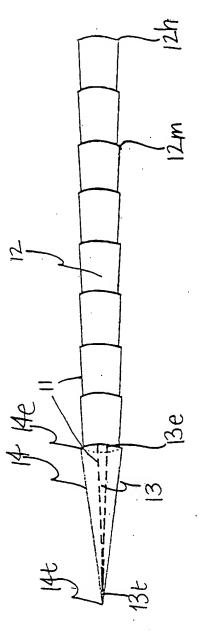
PCT/US00/13021

- 17. The endodontic post of claim 8 wherein the composite material comprises fiber reinforced composite material.
- 18. The endodontic post of claim 8 wherein the composite material comprises filler reinforced composite material.



Flowre 1

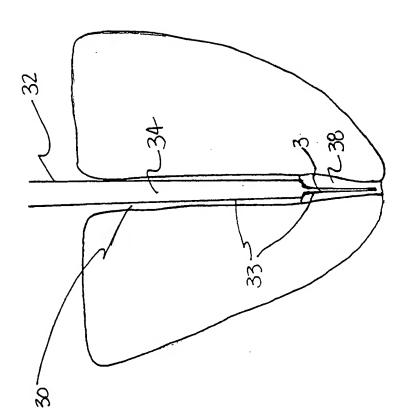
DOCID: <WO 0067659A1 L >



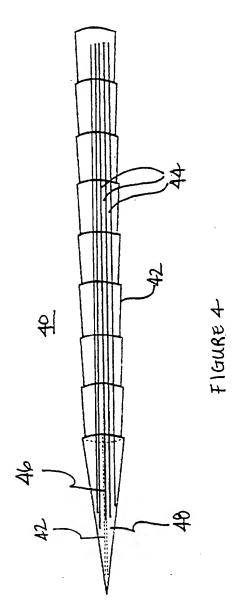
FLAURE 2

BNSDOCID: <WO _____ 0067659A1_1 >





3NSDOCID: <WO_____0067659A1_I_



VSDOCID: <WO_____0067659A1_1_:

PCT/US 00/13021

A. CLASSIF IPC 7	A61C5/04 A61C13/30		
	•		
	International Patent Classification (IPC) or to both national class	ification and IPC	
B. FIELDS	cumentation searched (classification system followed by classific	cation symbols)	
IPC 7	A61C		
Documentati	ion searched other than minimum documentation to the extent th	at such documents are included in the fields se	arched
Electronic da	ata base consulted during the international search (name of data	base and, where practical, search terms used)
EPO-In	ternal, WPI Data, PAJ		
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to claim No.
Х	US 5 595 486 A (MANOCHA ASHOK) 21 January 1997 (1997-01-21) column 1, line 64 -column 2, li	ne 5	1-4,6-11
	column 2, line 61-64		
	column 3, line 1,2 column 3, line 53-57		
	figures 1,4,7		
Y			17,18
Υ	FR 2 730 627 A (REYNAUD MARC) 23 August 1996 (1996-08-23) page 4, line 9-14 figures 1,4		17,18
		-/	
V Fur	ther documents are fisted in the continuation of box C.	Patent family members are listed	d in annex.
		<u> </u>	
"A" docum	ategories of cited documents : ent defining the general state of the art which is not dered to be of particular relevance	"T" later document published after the int or priority date and not in conflict with cited to understand the principle or the invention.	the application but
"E" earlier	document but published on or after the international date	"X" document of particular relevance; the cannot be considered novel or cannot	claimed invention at be considered to
which citatio	ent which may throw doubts on priority claim(s) or is cited to establish the publication date of another on or other special reason (as specified) tent referring to an oral disclosure, use, exhibition or	involve an inventive step when the d "Y" document of particular relevance; the cannot be considered to involve an is document is combined with one or m	ocument is taken alone ctaimed invention eventive step when the
P docum	means net published prior to the international filing date but than the priority date daimed	ments, such combination being obvious in the art. "8" document member of the same paten	ous to a person skilled
Date of the	actual completion of the international search	Date of mailing of the international se	earch report
9	August 2000	17/08/2000	
Name and	mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk	Authorized officer	
	Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Chabus, H	

Form PCT/ISA/210 (second sheet) (July 1992)

page 1 of 2

BNSDOCID: <WO____0067659A1_I_>

1 national Application No PCT/US 00/13021

•	ition) DOCUMENTS CONSIDERED TO BE RELEVANT		
ategory *	Citation of document, with indication where appropriate, of the relevant passages		Relevant to claim No.
(US 3 919 774 A (FISHMAN MARK J) 18 November 1975 (1975-11-18) column 1, line 40-44 column 1, line 67 -column 2, line 2 column 3, line 55-57 figures 2,3		1-3,6-8, 11
· -	US 5 564 929 A (ALPERT EDWARD L) 15 October 1996 (1996-10-15) cited in the application column 2, line 36-42 column 2, line 59-61 column 4, line 4,5 figure 6		5,17,18
١	US 5 074 792 A (BERNADAT GEORGES) 24 December 1991 (1991-12-24) 		
	·		
	,		
		,	
	, i		
			,
	·		

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

NSDOCID: <WO_____0067659A1_I_:

Information on patent family members

national Application No PCT/US 00/13021

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5595486	Α	21-01-1997	NONE	
FR 2730627	Α	23-08-1996	CA 2212953 A DE 69606167 D EP 0809475 A ES 2144230 T WO 9625119 A JP 11505439 T US 5989032 A	22-08-1996 17-02-2000 03-12-1997 01-06-2000 22-08-1996 21-05-1999 23-11-1999
US 3919774	Α	18-11-1975	NONE	
US 5564929	Α	15-10-1996	NONE	
US 5074792	A	24-12-1991	FR 2643812 A AT 91869 T DE 69002349 D DE 69002349 T EP 0385892 A ES 2043330 T FR 2669211 A	07-09-1990 15-08-1993 02-09-1993 04-11-1993 05-09-1990 16-12-1993 22-05-1992

Form PCT/ISA/210 (patent family annex) (July 1992)

3NSDOCID: <WO____0067659A1_1_>

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date 16 November 2000 (16.11.2000)

PCT

(10) International Publication Number WO 00/67659 A1

- (51) International Patent Classification7: A61C 5/04, 13/30
- (21) International Application Number: PCT/US00/13021

(22) International Filing Date:

12 May 2000 (12.05.2000)

(26) Publication Language:

English English

(30) Priority Data:

(25) Filing Language:

60/133,773

12 May 1999 (12.05.1999) US

- (71) Applicant: JENERIC/PENTRON INCORPORATED [US/US]: 53 North Plains Industrial Road, Wallingford, CT 06492-0724 (US).
- (72) Inventors: LOPEZ, Larry, A.; 522 Pleasant Valley Drive North. Boerne, TX 78006 (US). FINNIGAN, Bruce, A.; 177 Washington Street, Wallingford, CT 06492 (US). KARMAKER, Ajit: 321 South Elm Street, Wallingford, CT 06492 (US).

- (74) Agent: REIMER, Leah, M.; Cantor Colburn LLP, 55 Griffin Road South, Bloomfield, CT 06002 (US).
- (81) Designated States (national): AU, BR, JP, MX.
- (84) Designated States (regional): European patent (AT. BE. CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:

With international search report.

(48) Date of publication of this corrected version:

1 March 2001

(15) Information about Correction: see PCT Gazette No. 09/2001 of 1 March 2001, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ENDODONTIC POST SYSTEM

10a 13.

(57) Abstract: An endodontic post comprising a combined endodontic post and filling material tip in a single unit. To use the post unit, the device is placed in an oven or heater to heat and soften the thermoplastic material. The device will then be placed in a root canal that has been opened to a predetermined dimension by use of endodontic files, to seal the apical end. If necessary, the gutta percha can be compacted toward the apex, while it is still in the softened state, to ensure the apex is adequately sealed. The post is then cemented into place by lining the canal walls with a bonding agent and filling the interface between the post and the walls of the canal with a dual cure resin cement. This will result in a coronal seal of the canal via resin restorative material and an apical seal of the canal by means of gutta percha and sealant.

0.00/67659

5 .

10

15

1

ENDODONTIC POST SYSTEM

Field of the Invention

This invention relates to both the obturation of a root canal having undergone endodontic treatment and the simultaneous placement of an endodontic post system.

Background of the Invention

Endodontics or root canal therapy is that branch of dentistry dealing with the diseases of the dental pulp and associated tissues. One aspect of endodontics comprises the treatment of infected root canals, the removal of diseased pulp tissues, followed by the biomechanical modification and the subsequent filling of the pulp canal (root canal). Root canal therapy is generally indicated for teeth having sound external structures but having diseased, dead or dying pulp tissues. Such teeth may or may not generally possess intact enamel and dentin and be satisfactorily engaged with bony tissue. In such teeth, the pulp tissue and excised portions of the root should be replaced by a biocompatible substitute.

One technique for the preparation of a root canal involves creating a coronal access opening with a conventional dental drill. A tool is used for gross removal of pulp material from the root canal through the coronal access opening. The void formed is enlarged with reamers and/or files to result in a fully excavated cavity. Debris is removed from this cavity by flushing and the cavity is cleansed to remove

BNSDQCID: <WO_____0067659A1_IA>

2

all diseased tissue. Following chemical antisepsis, the excavated canal is ready for filling.

A basic method involves inserting a filling cone into a root canal and cementing therein to obturate the canal. Lateral condensation is a method in which several filling cones, a primary cone and auxiliary cones, are inserted into a root canal. The primary cone is inserted and cemented to the seat of the root canal. Using a tapered spreader, the primary cone is then squeezed against the side of the root canal and a second cone is inserted and cemented into place. This process is continued until the root canal is completely obturated, which can require up to 10 to 15 filling cones.

Vertical condensation of warm or hot gutta percha is yet another method of sealing root canals. After cementing a primary cone short of the apex of the root canal, heat application is alternated with a series of smaller and smaller pluggers until the gutta percha is moved to the apex. This is often possible when the smallest plugger approaches the apex of the tooth within 3 to 5 millimeters. The space is then backfilled. Lateral canals are packed and sealed as a consequence of lateral expansion of a wave of heated gutta percha. Alternatively, small segments of gutta percha can be used in this method that are inserted into the root canal, heated in order they can adhere to one another and each backfilled one at a time until the root canal is filled. All three of these methods, the single filling cone, lateral condensation and vertical condensation apply root canal cement or sealer around the individual cones or in between segments as a binding agent. Another method employs an injection gun that injects warm or hot gutta percha filling material into a root canal. The injector initially places heated gutta percha at the seat of the root canal which is then condensed with a plugger into the root tip. The injector then backfills the root canal by injecting additional gutta percha into the root canal until it is obturated. A similar method involves heating gutta percha on a flexible metal carrier used to insert the gutta percha into the root canal. The carrier may be a solid rod, or a hollow rod, situated in the center of a master cone. The rod is connected to a handle which may be removed by slipping it out of the hollow rod, or cutting it off if it is a solid rod.

NSDOCID: <WO_____0067659A1_IA>

5

10

15

20

25

5

10

15

20

25

30

While these systems provide for convenient and quick obturation of the canal, they pose a removal problem for the dentist who has to place a post.

Of all the methods used for obturating a canal, there is no device currently available that will allow a doctor to simultaneously obturate a root canal and place an endodontic post. Currently, an endodontist will perform the root canal procedure and the obturation during one patient visit. After the canal is obturated and temporarily sealed, the patient is frequently treated by a second dentist who will place the post. To do so, the gutta percha must be removed from the canal until only a portion (about 5 mm) from the apex remains to act as an apical seal. The rods inside the current systems make gutta percha removal much more difficult since the coronal portion of the gutta percha rod has to be removed to allow for the placement of the endodontic post. One way to overcome this problem has been to notch the obturating rod with a bur. Then, when the obturator is placed in the canal it is twisted, snapping off the apical portion. The longer coronal portion is removed. It is then re-introduced into the canal and the gutta percha is stripped off by means of pulling the rod through an endodontic stop. Since the endodontic stop is extremely narrow, the gutta percha is pulled from the rod as it is withdrawn and the gutta percha remains in the canal. It is subsequently condensed. As a result of this technique, the restoring dentist does not have to extract the rod and only has to remove the gutta percha to make room for the post. Some gutta percha may remain on the walls of the canal jeopardizing the bond strength of the post the radicular dentin. Reinfection of the treated tooth can be a problem because the endodontist performing the root canal procedure will seal the coronal opening with a temporary stopping agent which can leak oral fluids carrying bacterial into the canal opening.

It is desirable to reduce the steps and time involved in performing obturation and placement of a post in a root canal. It would be beneficial to limit the obturation and post placement to a single visit to the dentist or prosthodontist. It is advantageous to reduce and/or eliminate the leakage problems associated with poor sealing at the coronal end of the canal.

Summary of the Invention

NSDOCID: <WO 0067659A1_IA>

5

10

15

20

25

4

These and other objects and advantages are accomplished by the endodontic post of the present invention comprising a combined endodontic post and tip of filling material such as thermoplastic material in a single unit. To use the post unit, the tip of the device is softened by placing in an oven or heater to heat and soften the filling material or chemically treating to soften the material. The device is be placed in a root canal that has been opened to a predetermined dimension by use of endodontic files, to seal the apical end. If necessary, the gutta percha can be compacted toward the apex, while it is still in the softened state, to ensure the apex is adequately sealed. The post may then be cemented into place by lining the canal walls with a bonding agent and filling the interface between the post and the walls of the canal with a resin cement such as a dual cure cement, a light cure cement or a self cure cement such as Lute-It® dual cure luting cement or Cement-It® Universal cement, both available from Jeneric/Pentron Inc., in Wallingford, CT. This will result in a coronal seal of the canal via resin restorative material and an apical seal of the canal by means of gutta percha and sealant. The remaining portion of the post, extending supra-gingivally, will be used to build a core around it. Any excess will be cut off. One length of the device will be longer to accommodate the longer roots in anterior teeth. Another length will be shorter to accommodate smaller roots in the molar region. Various diameters may also be provided to accommodate the different sizes of root canals. The bonded flexible post may strengthen the tooth to prevent subsequent root fractures.

Brief Description of the Drawings

Features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

Figure 1 is an elevational view of a post in accordance with the invention;

Figure 2 is an elevational view of a post with an alternate carrier in accordance with the invention;

Figure 3 is a sectional view of a tooth showing a post of the invention placed

5

in the root canal; and

.5

10

15

20

25

30

Figure 4 is an elevational view of an alternate embodiment of a post in accordance with the invention.

Description of the Invention

As will be appreciated, the present invention provides a combination endodontic post and filler cone in a single unit. Reference is made to Figures 1 and 2 which show a post unit 10 comprising a post section 11 and a cone or tip section 14. Tip section 14 comprises a flexible rod or cone of biocompatible material for filling the apex of the canal. The filling material is typically a thermoplastic, chemo-plastic, or similar resinous material, such as gutta percha and is attached to post section 11 at the apical end 10a. Other examples of thermoplastic materials include but are not limited to thermoplastic methacrylate materials, polyurethanes, polypropylene and polyethylene.

The filling material may include additives typical in the dental field such as plasticizing, cariostatic, antibacterial, or other anti-inflammatory, biologically active or therapeutic materials.

Post section 11 comprises a main body or endodontic portion 12 and a carrier or apical portion 13 which is located at the apical end 10a of post unit 10. Main body 12 may be a solid rod of circular or other suitable cross-section comprising a substantially smooth surface or may comprise a plurality of frustoconical sections 16 arranged coaxially along the longitudinal axis of main body 12. Preferably, main body 12 has consistent width along the longitudinal axis thereof whereas frustoconical sections 16 each have the same tapered width and same length. It is possible to vary the width and/or length of main body 12 and/or vary the tapered width and/or length of frustoconical sections 16 along the longitudinal axis of main body 12. Main body 12 may include a larger head of any shape with or without a retentive design to provide support for a core thereon at the supracoronal end 12h as will be discussed hereinafter.

Carrier 13 is preferably an extension of main body 12 of post section 11 and is of very fine diameter to accommodate tip section 14 of thermoplastic material of post

VSDOCID: <WO_____0067659A1_IA>

6

unit 10. In one method of manufacture which will be discussed hereinafter, post section 11 is manufactured from a rod of material that is cut or machined at the apical end 10a to result in carrier 13 having a very small width or diameter in comparison to main body 12. Carrier 13 is of small diameter to allow enough area to form tip section 14 thereon, and also of enough strength and integrity to accommodate the filling material such as thermoplastic material. As stated above, carrier 13 is preferably an extension of main body 12 and is shown having constant diameter along the length thereof, but may be of any shape or size sufficient to hold tip section 14 thereon. Figure 2 shows an alternative carrier 13 of tapered width.

Post section 11 may be fabricated of any material to provide a flexible apical portion and a more rigid endodontic and/or coronal or supracoronal portion, such as metal, plastic, ceramic, polymeric, composite, or other material suitable for placement in the mouth. Composite materials include but are not limited to filler reinforced composite materials and fiber reinforced composite materials comprising the reinforcing component in a polymeric matrix material such as those composite materials listed in U.S. Patent Nos. 4,717,341 and 4,894,012 to Goldberg et al., U.S. Patent No. 6,039,569 to Prasad et al., U.S. Patent No. 6,030,220 to Karmaker et al, U.S. Patent No. 5,564,929 to Alpert, and U.S. Patent No. 5,919,044 to Sicurelli, Jr. et al., all of which are hereby incorporated by reference. The fiber reinforced composite material may comprise fibers in the form of long, unidirectional, continuous filaments which are preferably at least partially aligned and oriented along the longitudinal dimension of the component with alignment normal or perpendicular to that dimension also possible. The fibers may be of uniform or random length, unidirectional or multidirectional, or randomly dispersed, and may be as short as about 3 to about 4 millimeters (mm) or shorter. The fibers may also be in the form of fabric as set forth in copending Serial No. 09/280,760 filed March 29, 1999 and may include any of the attributes of the post described therein, the contents all of which are hereby incorporated by reference. Due to the improved structural integrity, the amount of fibers in the structural component preferably equals at least about 20% by weight (wt %) and preferably about 20 wt % to about 70 wt %. Possible reinforcing fibers, which are preferably used in accordance with U.S. Pat. Nos. 4,717,341 and

SDOCID: <WO_____0067659A1_IA>

5

10

15

20

25

7

4,894,012 to Goldberg et al. (which are herein incorporated by reference), include glass, ceramic, metal, carbon, graphite, polymeric such as cellulose, polyamide, aramid, polyester, polyaramid, acrylic, vinyl and modacrylic, polyolefin, polytetrafluorethylene, mixtures thereof, as well as other fibers known in the art. One preferred version of the device is comprised of unidirectional microfilamentous glass fibers bundled in a resin matrix.

In order to enhance the bond between the fibers and polymeric matrix, thereby enhancing the reinforcing effect, the fibers may be silanized or otherwise treated such as by grafting functional monomers to obtain proper coupling between the fibers and the resin matrix. Silanization renders the fibers hydrophobic, reducing the water sorption and improving the hydrolytic stability of the composite material, renders the fibers organophilic, improving wetting and mixing, and bonds the fibers to the polymeric matrix. Typical silane is A-174 (p-methacrylate propyl tri-methoxy silane), produced by OSI Specialties, New York The polymeric matrix is selected from those known in the art of dental materials, including, but not limited to, polyamides, polyester, polyolefins, polyimides, polyarylates, polyurethanes, vinyl esters or epoxy-based materials, styrenes, styrene acrylonitriles, ABS polymers, polysulfones, polyacetals, polycarbonates, polyphenylene sulfides, polyarylsulfides, acrylonitrile-butadiene-styrene copolymers, polyurethane dimethacrylates (hereinafter abbreviated to PUDMA), and the like. Preferred polymeric matrix materials include those based on acrylic and methacrylic monomers, for example those disclosed in U.S. Patent Nos. 3,066,112, 3,179,623, and 3,194,784 to Bowen; U.S. Pat. Nos. 3,751,399 and 3,926,906 to Lee et al.; and commonly assigned U.S. Pat. Nos. 5,276,068 to Waknine (which are herein incorporated by reference). An especially preferred methacrylate monomer is the condensation product of bisphenol A and glycidyl methacrylate, 2,2'-bis [4-(3-methacryloxy-2-hydroxy propoxy)-phenyl]propane (hereinafter abbreviated "BIS-GMA").

The polymer matrix, which typically includes polymerization initiators, polymerization accelerators, ultra-violet light absorbers, anti-oxidants, fluorescent whitening agents, free radical initiators, and/or other additives well known in the art, may be visible light curable, self-curing, dual curing, or vacuum, heat, or pressure

and the state of t

INSDOCID: <WO_____0067659A1_IA>

5

10

15

20

25

8

curable compositions, as well as any combination thereof. Heat and pressure or vacuum curable compositions include a heat cure initiator such as benzoyl peroxide, 1,1'-azobis(cyclohexanecarbo-nitrile) or other free radical initiators. The preferred polymeric matrix is a light and heat curable matrix, wherein light effects partial cure of the polymer matrix, while final curing is by heat under controlled atmosphere.

Fillers may be present in addition to or instead of fibers in an amount up to about 80 wt %, and preferably about 70 wt%. If fibers are present, the amount of filler is present in an amount of up to about 30 wt % of one or more fillers known in the art and used in dental restorative materials. Suitable fillers include those capable of being covalently bonded to the polymeric matrix itself or to a coupling agent that is covalently bonded to both. Fillers include silica, silicate glass, quartz, barium silicate, strontium silicate, barium borosilicate, strontium borosilicate, borosilicate, lithium silicate, amorphous silica, ammoniated or deammoniated calcium phosphate and alumina, zirconia, tin oxide, and titania, among other conventional fillers such as those disclosed in commonly assigned U.S. Pat. Nos. 4,544,359 and 4,547,531 to Waknine (which are incorporated herein by reference), while possible coupling agents include silanes, zirconates, and titanates. If the post is manufactured from a composite material, it is preferably in completely cured or hardened state.

Examples of metals useful as post section 11 include but are not limited to metals or alloys of Pd, Pt, Rh, Ir, Au, Ag, Ti, Co, Mo and alloys thereof such as AgPd, AuPtPd, TiAlFe, TiAlV,CoCrMo, stainless steel and brass. Ceramic materials useful in the fabrication of post section 11 include but are not limited to alumina, zirconia, mullite, spinel, porcelain, titania, lithium disilicate, leucite, amorphous glass, lithium phosphate, and combinations thereof, or any high strength ceramic material which can withstand the stresses created in the mouth.

In accordance with one method of manufacture herein, post section 11 (which includes main body 12 and carrier 13) is manufactured in any known method in the art and depending upon the material used for the manufacture of post section 11. Such methods include but are not limited to matched die processes, autoclave molding, resin injection molding (RIM), sheet, dough and bulk molding, press molding, injection molding, reaction injection molding, resin transfer molding

PNSDOCID: WO 006765941 IAS

5

10

15

20

25

WO 00/67659

(RTM), compression molding, open molding, hand rolling, dipping and rolling, pressing, extrusion, pultrusion and filament winding. As discussed above, post section 11 is formed into a rod-shaped unit or main body 12 having a very fine or thin apical end or carrier 13. The final shape of post section 11 may be formed simultaneously during the manufacturing process thereof. Alternatively, a rod shaped material may be manufactured and thereafter shaped by grinding, cutting, milling or the like into the desired shape and size. As shown in Figures 1 and 2, post section 11 is a rod-shaped component having a main body 12 comprising slightly tapered stepped sections 16, all of the same dimensions and whereby one end of post section 11 comprises a very narrow section, 13, which acts as the carrier for the filling material. As with sections 16, carrier 13 may be formed during the actual manufacture of main body 12 or thereafter by grinding, cutting or similar means. Although main body 12 includes sections 16 to aid in the retention of the post in the canal, main body 12 may be of any surface (e.g., smooth, partly smooth and partly frustoconical,) and shape suitable for placement in the canal such as in the case of smaller diameter posts whereby the ledges may be eliminated so as to maintain the structural integrity and strength of the post. Carrier 13 preferably comprises a smooth surface, although it is in no way limited to such and may be of any surface suitable for application of filling material thereon. The post may be provided in an opaque tooth color or it may be colored similar to a tooth's pulp for enhanced esthetics. The post may include an appropriate amount of raadiopaque material such as titanium oxide, barium sulfate, and similar materials known in the dental industry to insure xray documentation which may be added to the post material during manufacture thereof.

After post section 11 has been manufactured, carrier 13 of post section 11 is then coated with a filling material such as gutta percha to obtain cone section 14 thereon. The filling material may be applied by any known means such as dipping, injection molding, hand rolling, and the like.

The length of post unit 10 may vary depending upon the length of the root into which it will be inserted. It is preferable that post 10 be manufactured in a variety of lengths and widths to fit the many different root canals of dental patients and the

VSDOCID: -WO DOGZEGOA LA

10

15

20

25

10

differing lengths of the anterior (central and lateral incisors, bicuspids and premolars) and molar teeth. Preferably, post unit 10 is about 14 to about 31 mm in length and more preferably about 16 to about 25 mm in length. For the length parameter, post section 11 may be divided into three sections. Section 13 is the apical section and is about 3 to about 12 mm in length and preferably about 5 to about 8 mm in length. If section 13 is tapered as in Figure 2, the taper may be continuous at about 0.02 mm/per mm or less from the apical tip 13t to the end 13e of carrier 13, or preferably 0.04mm/per mm from the apical tip 13t to the end 13e of carrier 13. As stated above, carrier 13 is covered with a filling material such as a thermoplastic material which does not extend more than a few mm in length past the tip of 13 (13t). Main body 12 comprises a main section from point 13e to point 12m which is about 5 to about 13 mm in length and preferably about 7 to about 11 mm in length, and a supracoronal portion or "head" of post section 11 from point 12m to point 12h which about 2 to about 8 mm and more preferably about 4 to about 6 mm in length. The supracoronal portion of post unit 11 will be used to build a core upon which a crown will be placed. The main section (from 13e to 12m) of main body 12 of post section 11 may be slightly flexible to negotiate curved canals.

The diameter of post section 11 will also vary and range from about 0.02 to about 0.15 at the apical end (13t - 13e) and preferably from about 0.02 to about 0.09 at the apical end (13t - 13e). If carrier 13 is tapered, the diameter at 13t is in the range of about 0.02 to about 0.15 and preferably about 0.05 to about 0.16 mm and the diameter at 13e is in the range of about 0.2 to about 0.6 and preferably about 0.25 to about 0.4 mm. At the supracoronal end, the diameter is about 0.4 to about 0.6 and preferably about 0.5 to about 0.5 to about 0.5 to about 0.5 mm.

Tip section 14 comprising the filling material is about 0.5 to 1 mm longer than carrier 13, but the diameter of tip section 14 is tapered from point 13e to point 13t in accordance with ISO standards to correspond to current obturating techniques utilizing master cones of thermoplastic material. Accordingly, tip section 14 can be tapered at least 0.02 mm/per mm in accordance with ISO standards, and preferably 0.04 or 0.06 mm/per mm, or greater, measuring from tip 14t to 14e, for insertion into canals created with 0.02, 0.04.,0.06, or greater, tapered files. The diameter of tip 14

NSDOCID: <WO_____0067659A1_IA>

5

10

15

20

25

11

at point 14e is in the range of about 0.30 to about 2.0 mm and preferably 0.40 to about 1.5mm. The diameter of tip 14 at point 14 t is in the range of about 0.20 to about 1.0 mm and preferably about 0.25 to about 0.80 mm. When using the post unit in canals of 0.02 taper, the filling material such as thermoplastic material will be compressed by the canal and forced toward the coronal end of the canal. This will result in an apical seal in excess of 8 mm. The excess thermoplastic material can be removed with a heated instrument after it has hardened. When using the post unit in 0.06 tapered canals, the filling material can be condensed down toward the apex to fill the void created by the greater taper. This will result in an apical seal less than 8 mm, but in excess of 4 mm which is sufficient to maintain the apical seal.

To use the post unit, the device is placed in or near an oven or heater to heat and soften the filling material or dipped in a chemical solution such as chloroform to soften the filling material. The device will then be placed in a root canal that has been opened to a predetermined dimension by use of endodontic files, to seal the apical end. If necessary, the gutta percha can be compacted toward the apex, while it is still in the softened state, to ensure the apex is adequately sealed. The post is then cemented into place by lining the canal walls with a bonding agent and filling the interface between the post and the walls of the canal with a resin cement, such as a dual cure cement. This will result in a coronal seal of the canal via resin restorative material and an apical seal of the canal by means of gutta percha and sealant. The remaining portion of the post, extending supra-gingivally, will be used to build a core around it, and if necessary, for placement of a crown thereon. Any excess of the post will be cut off. One length of the device will be longer to accommodate the longer roots in anterior teeth. Another length will be shorter to accommodate smaller roots in the molar region.

Figure 3 shows a root canal 30 with post unit 32 therein. Post unit 32 comprises a post section 33 having a main body 34 and a carrier 36 that carries the filling material 38. As shown in Figure 3, the thermoplastic material 38 was softened prior to insertion and fills the apex of the canal.

In an alternate embodiment herein, reference is made to Figure 4 wherein a post unit 40 comprises a post section 42 fabricated of fiber reinforced composite

\SDOCID: <WO_____0067659A1_IA>

5

10

15

20

25

12

material wherein the fibers comprise optical fibers 44 such as glass fibers or a central core of a material such as metal which is able to transmit heat energy to the filling material. Glass fibers 44 extend out through post section 42 into carrier 46 and tip section 48. To use the post unit 40, the filling material 48 does not have to be softened or heated prior to insertion into the canal. Post unit 40 is inserted into the canal with tip 48 in its hardened state. A curing light or other heat source is applied to the coronal portion of the post, transmitting light or heat down toward the apex. Fibers 44 convert the light into heat or, alternatively, the core section transmits heat to the filling material. The heat then plasticizes the filling material such as gutta percha at the apex. The post is then pushed toward the apex using gentle finger pressure. This last step insures that the plasticized gutta percha is compressed apically and laterally, sealing the tooth and any lateral canals.

One of the benefits of this alternative embodiment is that it insures plasticized gutta percha is only introduced to the apical portion of the root and that the coronal portion of the root is free of gutta percha which could negatively affect the retentive strength of the post/core.

While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein. Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.

NSDOCID: <WO_____0067659A1_IA>

5

10

15

20

PCT/US00/13021

13

What is claimed is:

WO 00/67659

- 1. An endodontic post comprising:
- a post section; and
- a tip section, wherein the tip section comprises a filling material.
- 2.. The endodontic post of claim I wherein the tip section is integral to the post section.
- 3. The endodontic post of claim 1 wherein the post section comprises an apical portion and an endodontic portion and wherein the apical portion comprises a carrier.
- 4. The endodontic post of claim 3 wherein the carrier extends into the tip section.
 - 5. The endodontic post of claim 3 wherein the carrier is flexible.
- 6. The endodontic post of claim 3 wherein the apical portion of the post is narrower in diameter than the diameter of the endodontic portion.
- 7. The endodontic post of claim 3 wherein the post further comprises a supracoronal portion.
- 8. The endodontic post of claim 1 wherein the post section is fabricated of metal, plastic, composite, ceramic, glass or polymeric material.
- 9. The endodontic post of claim 1 wherein the filling material comprises a thermoplastic or chemoplastic material.
- 10. The endodontic post of claim 1 wherein the filling material comprises a polymeric material.

3DOCID: <WO_____0067659A1_IA

5

- 11. The endodontic post of claim 1 wherein the filling material comprises gutta percha.
 - 12. A method for restoring the root canal of a tooth comprising: preparing the root canal;

providing a post for insertion into the canal, whereby the post comprises a post section, and a tip section, wherein the tip section comprises a filling material;

softening the tip section of the post;

inserting the post into the canal, whereby the root canal is sealed by the filling material.

- 13. The method of claim 12 further comprising inserting a sealing material into the canal to bond the post to the canal.
- 14. The method of claim 12 further building a core on an end of the post that extends from the canal.
 - 15. The method of claim 14 further comprising placing a crown on the core.
 - 16. A method for restoring the root canal of a tooth comprising: preparing the root canal;

providing a post for insertion into the canal, whereby the post comprises a post section, and a tip section, wherein the tip section comprises a filling material, and wherein the post section comprises optical fibers, whereby the optical fibers extend into the tip section and wherein the upper end of the post section is the coronal end and the bottom of the tip section of the post is the apical end;

inserting the post into the canal;

applying a heat source to the coronal end of the post, whereby the heat source heats the fibers, and whereby the heated fibers soften the filling material located on the tip section, whereby the softened filling material seals the root canal.

BNSDOCID: <WO_____0067659A1_IA>

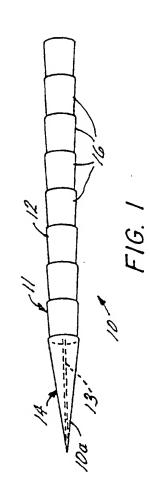
5

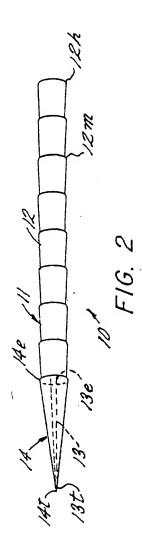
15

17. The endodontic post of claim 8 wherein the composite material comprises fiber reinforced composite material.

18. The endodontic post of claim 8 wherein the composite material comprises filler reinforced composite material.

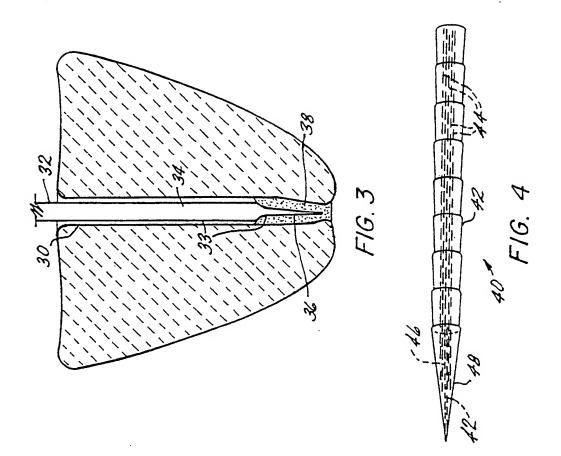
3NSDOCID: <WO_____0067659A1_IA>





RECTIFIED SHEET (RULE 91)

BNSDCCID: <WO ____0067659A1_IA>



RECTIFIED SHEET (RULE 91)

ISDOCID: <WO 0067659A1 IA3

national Application No PCT/US 00/13021

a. CLASSIF IPC 7	A61C5/04 A61C13/30		
	International Patent Classification (IPC) or to both national class	ification and IPC	
	SEARCHED	incator allo inc	
	cumentation searched (classification system followed by classific	cation symbols)	
IPC 7	A61C	·	
Documentat	ion searched other than minimum documentation to the extent th	at such documents are included in the fields se	arched
Electronic d	ata base consulted during the international search (name of data	base and, where practical, search terms used)
EPO-In	ternal, WPI Data, PAJ		
C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to claim No.
Х	US 5 595 486 A (MANOCHA ASHOK) 21 January 1997 (1997-01-21) column 1, line 64 -column 2, li	ne 5	1-4,6-11
	column 2, line 61-64 column 3, line 1,2 column 3, line 53-57		·
	figures 1,4,7	•	
Y			17,18
Υ·	FR 2 730 627 A (REYNAUD MARC) 23 August 1996 (1996-08-23) page 4, line 9-14 figures 1,4		17,18
		-/	
X Fur	ther documents are listed in the continuation of box C.	Patent family members are listed	in annex.
"A" docum consi "E" earlier filing "L" docum which citati "O" docum other "P" docum	ategories of cited documents: tent defining the general state of the art which is not dered to be of particular relevance document but published on or after the international date tent which may throw doubts on priority claim(s) or n is cited to establish the publication date of another on or other special reason (as specified) nent referring to an oral disclosure, use, exhibition or means the published prior to the international filing date but than the priority date claimed	"T" later document published after the int or priority date and not in conflict with cited to understand the principle or the invention." "X" document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the different comment of particular relevance; the cannot be considered to involve an indocument is combined with one or ments, such combination being obvious in the art. "&" document member of the same paten.	the application but learny underlying the claimed invention to be considered to comment is taken alone claimed invention trentive step when the one other such docu- bus to a person skilled
	actual completion of the international search	Date of mailing of the international se	earch report
9	9 August 2000	17/08/2000	
Name and	mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.	Authorized officer Chabus H	

Form PCT/ISA/210 (second sheet) (July 1992)

page 1 of 2

BNSDOCID: <WO_____0067659A1_IA>

national Application No PCT/US 00/13021

	Relevant to claim No.
Citation of document, with indication, where appropriate, of the relevant passages	Tioloval a to diamit 140.
US 3 919 774 A (FISHMAN MARK J) 18 November 1975 (1975-11-18) column 1, line 40-44 column 1, line 67 -column 2, line 2 column 3, line 55-57 figures 2,3	1-3,6-8,
US 5 564 929 A (ALPERT EDWARD L) 15 October 1996 (1996-10-15) cited in the application column 2, line 36-42 column 2, line 59-61 column 4, line 4,5 figure 6	5,17,18
US 5 074 792 A (BERNADAT GEORGES) 24 December 1991 (1991-12-24)	
	18 November 1975 (1975-11-18) column 1, line 40-44 column 1, line 67 -column 2, line 2 column 3, line 55-57 figures 2,3 US 5 564 929 A (ALPERT EDWARD L) 15 October 1996 (1996-10-15) cited in the application column 2, line 36-42 column 2, line 59-61 column 4, line 4,5 figure 6 US 5 074 792 A (BERNADAT GEORGES)

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

Information on patent family members

national Application No PCT/US 00/13021

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5595486	A	21-01-1997	NONE	
FR 2730627	A	23-08-1996	CA 2212953 A DE 69606167 D EP 0809475 A ES 2144230 T WO 9625119 A JP 11505439 T US 5989032 A	22-08-1996 17-02-2000 03-12-1997 01-06-2000 22-08-1996 21-05-1999 23-11-1999
US 3919774	Α	18-11-1975	NONE	
US 5564929	Α	15-10-1996	NONE	
US 5074792	A .	24-12-1991	FR 2643812 A AT 91869 T DE 69002349 D DE 69002349 T EP 0385892 A ES 2043330 T FR 2669211 A	07-09-1990 15-08-1993 02-09-1993 04-11-1993 05-09-1990 16-12-1993 22-05-1992

Form PCT/ISA/210 (patent family annex) (July 1992)

BNSDOCID: <WO_____0067659A1_IA>